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PATENT Attorney Docket No. 015280-347100US

Assistant Commissioner for Patents Washington, D.C. 20231

On 11-22-02

TOWNSEND AND TOWNSEND and CREW LLP

By: My (leg)

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**TECH CENTER 1600/2900** 

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Robert F. Bonner et al.

Application No.: 09/456,042

Filed: December 6, 1999

For: DESIGNS FOR NON-CONTACT

LASER CAPTURE MICRODISSECTION

Examiner: G. Gabel

Art Unit:

1641

**DECLARATION OF** 

DALE D. BERKLEY, J.D., Ph.D.

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Dr. Dale Berkley, the Declarant deposes and says:

I am a Technology Development Coordinator (TDC) within the National Institutes of Health (NIH). A copy of my curriculum vitae is attached hereto as Exhibit 1.

I lodged this Declaration to establish due diligence in filing the above-entitled patent application. Specifically, I lodged this Declaration to establish that between December, 1997 and the beginning of July 1998, the processing of Precision Laser Capture Microdissection Utilizing Short Pulse Length, Provisional Patent Application 60/094,871 on July 30, 1998 occurred in accordance with normal procedures and did not include undue delay. This Provisional Patent Application ultimately became US Patent

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6,420,132. Specifically, our patent attorneys, Townsend and Townsend and Crew, were authorized to file the patent application in early July 1998 and completed the filing of this patent application in a provisional format on July 30, 1998 as Provisional Patent Application 60/094,871. As evidenced by the co-filed Declaration of Dr. Robert Bonner, the filing occurred with dispatch.

Attached hereto as Exhibit 2 is PHS Employee Invention Report E-070-98/0. Turning to page one of this report, it will be seen that the report is entitled Designs for Noncontact Laser Capture Microdissection. As can be seen, the report is numbered in discrete sections. The first, formal section, is numbered pp. 1 through 6 and includes, on page 5, the witness signatures of Dr. Robert Bonner and Dr. Seth Goldstein. The date of the signatures is December 23, 1997. The second, written section, is numbered pp. 1 through 6 and includes a general description of the parameters of this invention.

This particular PHS Employee Invention Report was processed by my predecessor, John Fahner-Vitelhic, in accordance with regular procedures in place during the time the report was filed and continuing to this day. This was an interval of about six months during which time due diligence was exercised as evidenced below.

A PHS Employee Invention Report is typically first submitted by the PHS employee to his Institute's Technology Development Coordinator (TDC). The TDC undertakes a preliminary formal review of the invention, making sure that the cited references are attached and that the EIR (Employee Invention Report) is properly executed. The EIR is then forwarded to the Director of the Office of Technology Transfer (OTT) where it is distributed to one of three working groups (General Medicine, Cancer, Infectious Diseases and Mechanical Engineering). Typically the time between the submission of the EIR until it is received by OTT is up to two months.

The EIR is then assigned to a Technology Licensing Specialist for a preliminary patentability and marketing assessment. Occasionally, a formal patentability opinion is procured from one of OTT's contract law firms and, after the opinion is delivered, the Technology Specialist drafts a memorandum recommending a course of action for protecting the invention. This memorandum is first reviewed by the working group

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manager and then forwarded to the TDC. The time from receipt by the Technology Specialist until a recommendation is issued is typically one-half to two months.

The TDC then uses the OTT's recommendation to draft his or her own recommendation for the Institute's Scientific Director. The Scientific Director then approves or disapproves the recommendation and forwards the matter to the TDC, who communicates the Director's recommendation to OTT. Only then can a patent application be ordered from one of the contracting attorneys. The time from the Technology Specialist's forwarding the memorandum to the TDC until a recommendation to proceed is received from the TDC is typically two months.

I have examined the file in this application. The time periods set forth in this memorandum track the approval and filing of the patent application under my predecessor, John Fahner-Vitelhic.

Further declarant sayeth not.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Dated: Novauser 8, 2002

Dale D. Berkley, J.D., Ph.D.